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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/614,105 | 07/08/2003 | Isao Yamazaki | KAS-187 | 7653 |
| 7590 | 08/23/2006 | | EXAMINER | |
| MATTINGLY, STANGER & MALUR, P.C. Suite 370 1800 Diagonal Road Alexandria, VA 22314 | | | TURK, NEIL N | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1743 | |

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/614,105 | YAMAZAKI ET AL. |
| | Examiner Neil Turk | Art Unit 1743 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) 9 is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/26/04, 7/8/03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Objections

Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 contains duplicate limitations from claim 8. It appears that when applicant amended the dependency of claim 8, claim 9 became a duplicate claim.

Double Patenting

Applicant is advised that should claims 8 and 9 be found allowable, claim 9 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). It appears that when applicant amended the dependency of claim 8, claim 9 became a duplicate claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not disclose how the dispensing of reagents is accomplished without movement of the reaction disk, as recited in the above claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 recites the limitation "said plural reaction disks" in line 6 of claim 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation that reads "a reagent dispensing probe as defined in said claim and a reagent disk as defined in said claim" is indefinite because it is unclear as to which claim is being referred to.

Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. It is unclear how the reagent dispensing into the reaction disk without moving the reaction disk is accomplished. The specification is silent to this function and it is therefore unclear if the reagent dispensing probes comprise additional structural elements that enable such dispensing or if other elements or functions are required for such a process. Additionally it is unclear if "without moving said reaction disk" is meant to mean that during the actual time that liquid is being dispensed the reaction disk is stationary, or if the reaction disk is not to move during a period of time between a different dispensing operation. For purpose of examination, examiner will interpret "without moving said reaction disk" to mean that the disk remains stationary while reagent is being dispensed into reaction vessels of the reaction disk.

Claim 10 recites the limitation "said plural reagent discs" in line 3 of claim 10. There is insufficient antecedent basis for this limitation in the claim. Examiner asserts that applicant may have meant to recite, "wherein at least one of said plural reagent containers is arranged..." At present, examiner will interpret claim 10 to read as asserted here.

Claim 11 recites the limitation "said reagent dispensing probes" in lines 2-3 of claim 11. There is insufficient antecedent basis for this limitation in the claim. Claim 1, from which claim 11 depends only recites "a reagent dispensing probe", not a plurality of reagent dispensing probes that is currently recited in claim 11.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Umetsu (5,051,238). Umetsu discloses an automatic analyzing system. Umetsu discloses a sample table (first reagent disk) 315, having sample vessel pockets 314 arranged at intervals around the circumference (lines 21-28, col. 3, fig. 1). Umetsu also discloses a reagent table 310 (second reagent disk) having reagent vessels 311 disposed around the circumference (lines 29-36, col. 3, fig. 1). Umetsu also discloses that the reagent table 310 has a plurality of reagent pack pockets 312a, each having receiving a reagent pack 312 which includes three reagent vessels 311, charged with different reagents (lines 35-42, col. 3, fig. 1). Umetsu further discloses a reaction table 302 having a plurality of reaction vessel pockets 301 arranged in the circumferential direction (lines 43-50, col. 3, fig. 1). Umetsu discloses that the reaction vessel pockets 301 receive reaction vessels 301' (lines 60-63, col. 3, fig. 1). Umetsu additionally discloses that a single pipetting device 317 is disposed between the reaction table 302 and the reagent table 310; the pipetting device has a pivotable arm 300 (capable of necessary movements between the respective tables) about the axis of shaft 304, and a probe 318 having liquid removing and discharging function (lines 65-67, col. 3; lines 1-12, col. 4, fig. 1). Umetsu discloses that the pipetting device is capable of moving

samples from sample vessels 314' and discharging them into reaction vessels 301'; the pipetting device can also suck reagents from reagent vessels 311 and discharging them into reaction vessels 301' (lines 1-19, col. 4, fig. 1). Umetsu further discloses that the reaction table carries a fluorescent photometer 325; light emitted from light source 326 is applied to the successive reaction vessels and the light transmitted through the reaction vessels is measured by the fluorescent photometer 325 (or light absorbing photometer), to thereby analyze a sample (lines 20-27, col. 4, fig. 1). Umetsu discloses the operation and manner of use of the analyzing system in figure 1 as described above in lines 38-67 of col. 4 to line 57 of column 5.

With regard to claim 5, it is only required that a reagent dispensing probe be able to dispense desired plural reagents into desired one of said plural reaction cells on said reaction disk without moving said reaction disk. The dispensing operation of Umetsu discloses the pipetting device 317 transfers reagents from reagent packs 312 (within reagent vessel 311) to successive reaction vessels 301'. Umetsu discloses that a first reagent is removed and delivered to reaction vessel 301' and then, after washing the probe, a second reagent is removed and delivered to reaction vessel 301' (the disk is stationary during this process) (lines 15-45, col. 5, fig. 1). Examiner also asserts that during dispensing operations disclosed in Umetsu, the reaction disk is kept stationary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1743

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umetsu in view of Ginsberg. Umetsu has been discussed above.

Umetsu does not disclose a plurality of sets composed of a sample dispensing probe, reagent dispensing probe, and a reagent disk. Umetsu does not disclose a plurality of dispensing probes.

Ginsberg discloses first and second reagent dispensing arms 34 and 40 (from reagent tray 16) for dispensing a first and second reagent respectively to determined locations of cuvettes at reagent dispensing locations 18" and 18" on disk 12 (the cuvette disk, aka reaction disk, is stationary while first and second reagent are dispensed) (lines 59-67, col. 5; lines 1-67, col. 6, fig. 1). Ginsberg also discloses a sample dispensing arm 28 (from sample tray 14) with a probe 66 for picking up and dispensing of sample aliquots (lines 9-68, col. 4, fig. 1). Ginsberg discloses that first and second reagent dispensing arms 34, 40 and sample dispensing arm 28 are

controlled in by motors for their movement to respective cuvette sites and tabs are read by a reader to determine when they are in the pick-up position (col. 4-6). Ginsberg also discloses method which involves the use of the first and second reagent dispensing arms 34, 40 and sample dispensing arm 28 in aspirating and dispensing of separate sample/reagent combinations to subsequent different cuvettes 18 for different reaction observations (col. 16-26, claims 1-57). Examiner interprets the individual combinations of reagent dispensing arms 34, 40, sample dispensing arm 28, and respective reagent disk used to form separate reaction mixtures constitutes the sets as claimed in claim 4, such that multiple analyses are being created through the respective combinations.

It would have been obvious to modify the Umetsu device to include a plurality of dispensing probes such as taught by Ginsberg so as to allow the Umetsu device to more quickly dispense the multiple reagents contained in the reagent vessels to the reaction vessels. It would have been obvious to modify the Umetsu device to include sets composed a sample dispensing probe, reagent dispensing probe, and reagent disk such as taught by Ginsberg in order to provide for multiple, different reaction mixtures to be formed for analysis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Turk whose telephone number is 571-272-8919. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

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